DETAILED ACTION

The following is a Final Office action in response to communications received on 08/24/09. Claim 35 was amended. Claims 35-45 are currently pending and addressed below.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/24/09 has been entered.

Drawings

2. The amended drawings were received on 08/24/09. These drawings are sufficient to overcome the drawing objection of the previous Office action.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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- 4. Claims 35-41, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz et al. WO 01/05338 in view of Pope et al. (6,676,704) further in view of McLean et al. 2004/0054418.
- 5. Regarding Claims 35-38, Bunz discloses a hip joint prosthesis comprising an inner sliding cup made of ceramic material that is surrounded on its outside by a plastic covering (abstract).

However, Bunz does not disclose surface semicircular depressions arranged circumferentially on the outside of the sliding cup.

Pope discloses a substrate for attachment to a femoral head and an acetabular comprising of spherical segment depressions with a diameter from .001 in. up to .750 in. (col. 43, II. 15-35), undulating in section, and circumferentially arranged (fig. 3c) for the purpose of creating a mechanical interlock between adjacent layers of the hip prosthesis (col. 41, II. 23-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sliding cup of the sandwich insert of Bunz with the undulating depressions of Pope in order to achieve a mechanical interlock as taught by Pope (col. 41, II. 23-25).

Bunz in view of Pope discloses the invention as claimed and as discussed above. However, Bunz in view of Pope does not disclose a metal shell around the plastic covering.

McLean discloses a hip prosthesis comprising a metal shell with a polyethylene liner adapted to fit tightly in the shell (paragraph 3).

It should be noted that the use of plastic liner inside or metal shells is widely known and practiced in the art. It would have been obvious to one of ordinary skill in the art to modify the device of Bunz with a metal shell in order to provide articulating surface for a femoral head as disclosed my McLean (paragraph 3).

- 6. Regarding Claim 39, Bunz illustrates a sliding cup (1) having a stepped structural form on its outside (fig. 2).
- 7. Regarding Claim 40, Bunz illustrates the plastic covering embracing the sliding cup at its pin end (fig. 2).
- 8. Regarding Claim 41, Bunz illustrates a collar of the plastic covering 5 that rests on the upper side of the sliding cup and covers almost half of the upper edge (fig. 2).
- 9. Regarding Claim 43, Bunz in view of Pope discloses the invention as claimed and as discussed above. However, Bunz as modified by Pope do not disclose an eccentric relationship between the inner and outer form of the sliding cup.

McLean et al. discloses an eccentric relationship between the inner surface 30 and the outer surface 26 of an articulating surface shell in order to improve migration and other properties of the prosthesis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sliding cup of Bunz in view of Pope with the eccentric relationship of McLean in order to optimize articulating wear properties of the sliding cup relative to the femoral head.

10. Regarding Claim 44, Bunz in view Pope and further in view of McLean discloses the invention as claimed and discussed above, however Bunz does not positively recite the range claimed in Claim 34. It has been held that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Peterson*, see MPEP 2144.05, Part II, section A.

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11. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz et al. WO 01/05338 in view of Pope et al. '704 in view of McLean et al. 2004/0054418 and further in view of Teinturier (5,041,140).

Bunz in view of Pope in view of McLean discloses the invention as claimed and as discussed above. However, Bunz in view of Pope does not disclose a press fit between the sliding cup and the plastic covering.

Teinturier teaches a press fit between a plastic cup 42 and a metal shell in order to allow the acetabulum unit to adapt to deformations of the skeleton and adapt to them (col. 4, II. 59-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sliding cup of Bunz in view of Pope by press fitting it into the plastic covering as taught by Teinturier in order to allow for deformation of the skeleton by the hip prosthesis.

12. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz et al. WO 01/05338 in view of Pope et al. (6,676,704).

13. Bunz discloses a hip joint prosthesis comprising an inner sliding cup made of ceramic material that is surrounded on its outside by a plastic covering (abstract).

However, although implied, Bunz does not disclose surface "structuring". It should be noted that the term "structuring" does not define a particular structure; however, the Examiner is examining this limitation as best understood.

Pope discloses a substrate for attachment to a femoral head and an acetabular comprising of spherical segment depressions with a diameter from .001 in. up to .750 in. (col. 43, II. 15-35), undulating in section, and circumferentially arranged (fig. 3c) for the purpose of creating a mechanical interlock between adjacent layers of the hip prosthesis (col. 41, II. 23-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention combine the sliding cup of the sandwich insert of Bunz with the undulating depressions of Pope in order to achieve a mechanical interlock as taught by Pope (col. 41, II. 23-25).

Response to Arguments

14. Applicant's arguments filed 08/24/09 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to combine the inventions of Bunz and Pope. The Examiner respectfully disagrees. The device of Pope has disclosed a method of interlocking layers of an orthopedic implant. It uses a method that is substantially equivalent to that claimed by the Applicant because of the use of undulations on a surface locking to depressions on a facing surface. Regardless of the

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location of the two surfaces outside of their relation to each other, this method solves the same problem as that of the Applicant which is achieving a mechanical interlock. Substituting the interlock method of Bunz with the interlocking method of Pope would have been obvious to one or ordinary skill in the art as both of the methods of achieving mechanical interlock were known and used in the art at the time of Applicant's invention. As previously stated on the record in previous Office actions, the Pope reference is used to show an alternate method of achieving mechanical interlock and that substituting one for another would have been obvious as both are known to accomplish such a mechanical interlock. This is not an example of impermissible hindsight.

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- 15. The Applicant also argues that a modification of Bunz with the undulations of Pope would cause the device of Bunz to be unfit for its intended purpose. Although the Applicant argues this, the Applicant gives no reason for making such an assertion. The undulations of Pope would result in a mechanical interlock between the ceramic sliding surface and plastic covering of Bunz, which is the exact intent of Bunz.
- 16. Applicant also argues that Pope teaches away from the use of the materials of Bunz. The Examiner respectfully disagrees. Pope's arguments refer to materials being used at an interface between a femoral head component and an acetabular bearing surface which would be subject to a completely different magnitude of forces because of the articulation between the two components. These arguments do not pertain to the use of layers in an acetabular insert.

Conclusion

17. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason-Dennis Stewart/ Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738